Appendix A—**Chronic Pain Medical Treatment Guidelines** supplements the necessity statement and justification for Section 9792.24.2. Chronic Pain Medical Treatment Guidelines (DWC 2008) set forth in the Initial Statement of Reasons.

General Overview

The Chronic Pain Medical Treatment Guidelines, Section 9792.24.2, et al., consists of two parts. Part 1 is entitled Introduction, and Part 2 is entitled Pain Interventions and Treatments. The chronic pain medical treatment guidelines replace the ACOEM's Practice Guidelines' Chapter 6—*Pain, Suffering, and the Restoration of Function* (Chapter 6) relating to chronic pain. The chronic pain medical treatment guidelines are adapted from the Work Loss Data Institute's Official Disability Guidelines (ODG) Treatment in Workers' Comp – Chapter on Pain. The version adapted is dated October 31, 2007, with the permission of the Work Loss Data Institute. The Work Loss Data Institute has provided its ODG chapter on pain version to the Division of Workers' Compensation (DWC) at no cost.

Because the Work Loss Data Institute continuously revises its chapter on pain, it is important for the DWC to utilize the last available version of ODG's chapter on pain as a basis for the DWC's Chronic Pain Medical Treatment Guidelines since DWC is precluded from automatically adopting future updates of the chapter without formal rulemaking. DWC used the last available copy when it commenced its rulemaking, thus the version is dated October 31, 2007. Future updates will be integrated into the medical treatment utilization schedule (MTUS) utilizing the formal rulemaking process. The selection of the ODG chapter on pain was based not only on the fact that the ODG guidelines were determined to meet the requirements of the statute (Lab. Code, § 5307.27) by RAND in its publication entitled, *Evaluating Medical Treatment Guideline Sets for Injured Workers in California,* RAND Institute for Civil Justice and RAND Health, 2005 (2005 RAND Report; see, Table 4, p. 21; Table 4.2, p. 27), but upon thorough review of the entire pain chapter by the Division of Workers' Compensation (DWC), the Medical Evidence Evaluation Advisory Committee (MEEAC), and designated subject matter experts.

Part 1: Introduction

The DWC drafted an introduction to the chronic pain medical treatment guidelines that best integrates the guidelines into the MTUS. The DWC introduction replaces the ODG introduction found in the ODG chapter on pain.

The introduction states that these guidelines focus primarily on chronic pain and replace Chapter 6 of the ACOEM Practice Guidelines (Chapter 6). It clarifies that the clinical topics sections of the MTUS will address pain in the context of the injured body part and

will guide the acute and subacute management of the initial injury. It makes clear that the chronic pain medical treatment guidelines apply to patients with a painful condition that remains unresolved with initial and subacute care after the clinical algorithms found in each body part section has been followed.

The introduction further explains how the chronic pain medical treatment guidelines apply. It states that generally, providers should begin with an assessment of the presenting complaint and a determination as to whether there is a "red flag for a potentially serious condition" which would trigger an immediate intervention. Upon ruling out a potentially serious condition, conservative management is provided and the patient is reassessed over the next 3-4 weeks. If the complaint persists during this interval, the treating physician needs to reconsider the diagnosis and decide whether a specialist evaluation is necessary. It further indicates that the chronic pain medical treatment guidelines apply to patients who fail to recover and continue to have persistent complaints without definitive treatment, such as surgical options. It clarifies that this provides a framework to manage all chronic pain conditions, even when the injury is not addressed in the clinical topics section of the MTUS.

The introduction also explains that the chronic pain medical treatment guidelines consist of two parts. Part 1 is the introduction, and Part 2 consists of pain interventions and treatments. It clarifies that, with a few exceptions, Part 2 is primarily an adaptation of evidence-based treatment guidelines from the ODG chapter on pain. The version adapted by the DWC is dated October 31, 2007, and it has been adapted with Work Loss Data Institute's permission. The introduction further informs the public that any individual treatment topic not adapted directly from ODG is labeled "[DWC]". However, some ODG individual treatment topics were relocated or the topic heading was modified but the text beneath the topic heading was left intact. In these instances, the individual treatment topics were labeled "[ODG]".

Definitions:

Chronic Pain:

The Introduction contains various terms' definitions. "Chronic pain" is defined as "any pain that persists beyond the anticipated time of tissue healing." The definition was crafted from *Bonica's Management of Pain,* Third Edition, John D. Loeser, et al. (2001). In Chapter 2, authored by Dennis C. Turk and Akiko Okifuji and entitled *Pain Terms and Taxonomies of Pain,* chronic pain is discussed at pp. 17-18, in part, as follows:

> Discussions of pain involve many terms. The meaning and connotation of these different terms may vary widely….
>
> ***

> *Pain, acute/pain, chronic:* Definitions of acute, chronic, recurrent, and cancer pain are not included in the IASP list of pain terms. We believe, however, that it is important to clarify these as they are commonly used in the literature.
>
> Traditionally, the distinction between acute and chronic pain has relied on a single continuum of time with some interval since the onset of pain used to designate the onset of acute pain or the transition point when acute pain becomes chronic. The two most commonly used chronological markers used to denote chronic pain have been 3 months and 6 months since the initiation of pain: however, these distinctions are arbitrary.
>
> Another criterion for chronic pain is 'pain that extends beyond the expected period of healing.' This is relatively independent of time because it considers pain as chronic even when it has persisted for a relatively brief duration.

Thus, the term "chronic pain" has been defined as "any pain that persists beyond the anticipated time of tissue healing." This definition corresponds with the MTUS framework in that it allows the DWC to utilize the ACOEM's clinical algorithms to define the transition point between acute and chronic.

The Introduction further clarifies that pain mechanisms can be broadly categorized as nociceptive or neuropathic pain, and defines these terms for the benefit of the public.

Nociceptive pain

The term "nociceptive pain" has been defined as "pain caused by activation of nociceptors, which are sensory neurons found throughout the body." A nociceptor is "a receptor preferentially sensitive to a noxious stimulus or to a stimulus which would become noxious if prolonged." This definition is crafted from a standard definition from the International Association of Pain. (See, http://www.iasp-pain.org/AM/Template.cfm?Section=General_Resource_Links&Template=/CM/HTMLDisplay.cfm&ContentID=3058#Nociceptor.)

Neuropathic pain

The term "neuropathic pain" has been defined as "pain initiated or caused by a primary lesion or dysfunction of the nervous system." Normal nociception would not be considered dysfunction of the nervous system. This definition is also crafted from a standard definition from the International Association of Pain. (See, http://www.iasp-

pain.org/AM/Template.cfm?Section=General_Resource_Links&Template=/CM/HTMLDisplay.cfm&ContentID=3058#Nociceptor.)

Overview

The overview section of the introduction informs the public that chronic pain is a significant health problem and the experience of pain is a complex phenomenon. It further informs the public that the field of pain research is rapidly evolving and there are multiple models to explain chronic pain. These models increasingly recognize that pain is ultimately the result of the pathophysiology plus the psychological state, cultural background/belief system, and relationship/interactions with the environment (workplace, home, disability system, and health care providers). Further, the overview indicates that current research is investigating the neurobiological causes for persistent pain and how structural and functional changes in the central nervous system may serve to amplify and maintain the experience and disability of certain pain conditions.

The overview further discusses pain mechanisms which help to match the appropriate treatment to the type of pain. Because the experience of pain is a complex phenomenon, the overview reviews various models to provide a conceptual framework for physicians, patients, families, healthcare facilities, carriers, and compensation systems for understanding pain. These models include acute vs. chronic pain model, illness behavior model, biomedical vs. biopsychosocial model, and medical vs. self-management model.

Risk Stratification

Risk stratification is a method to identify patients with chronic pain early and to determine their level of need. This section describes how to identify delayed recovery during the transition from acute to chronic. The section further discusses patients with intractable pain, which represents a subset of patients who are refractory to treatment but should have access to proper treatment for their pain as required by California law.

Assessment Approaches

This section describes the importance of taking a thorough history and physical examination in clinical assessment and treatment planning for the patient with chronic pain. It further provides for the need to make a psychosocial assessment in treatment planning. It states that for patients with a complex presentation, psychosocial factors have proven better predictors of chronicity than clinical findings.

Functional Restoration Approach to Chronic Pain Management

This section provides that functional restoration is an established treatment approach that aims to minimize the residual complaints and disability resulting from acute and/or chronic medical conditions. It also states that functional restoration can be considered if there is a delay in return to work or a prolonged period of inactivity. It further states that functional restoration is the process by which the individual acquires the skills, knowledge and behavioral change necessary to avoid preventable complications and assume or re-assume primary responsibility for his or her physical and emotional well-being. It indicates that multiple treatment modalities (pharmacologic, interventional, psychosocial/behavioral, cognitive, and physical/occupational therapies) are most effectively used when undertaken within a coordinated, goal-oriented, functional restoration approach.

Pain Outcomes and Endpoints

This section clarifies it is essential to understand the extent to which function is impeded by pain. Pain is subjective and it cannot currently be readily validated or objectively measured. Further, subjective reports of pain severity may not correlate well with its functional impact. Thus, the aim of chronic pain treatment is to return to function rather than complete or immediate cessation of pain. On the other hand, physicians treating in the workers' compensation system must be aware that just because an injured worker has reached a permanent and stationary status or maximal medical improvement, this does not mean that they are no longer entitled to future medical care.

Conclusion and References.

The conclusion section recaps the concepts elaborated in the text of the introduction. The reference section lists literature citations supporting the text of the introduction.

Part 2: Pain Interventions and Treatments

Part 2 of the Chronic Pain Medical Treatment Guidelines (DWC 2008) provides guidelines for pain interventions and treatments. Part 2 consists by and large of individual treatment topics contained in the ODG chapter on pain, version dated October 31, 2007. For some individual treatment topics in the ODG chapter on pain, however, the reviewers wanted to review the treatment recommendations. Evidence-based reviews (EBRs) were conducted on these topic areas to determine the most appropriate treatments and new individual treatment recommendations based on the EBRs are included in the guidelines. Further, there are topic areas that the ODG chapter on pain does not cover. EBRs were conducted on these areas and individual treatment topics are also included. EBRs were conducted as well on the ODG chapter on pain individual treatment sections determined by ODG to be "under study." Based on the independent EBRs conducted on these treatment sections, decisions were made as to whether or not to include these individual

treatment topics into the chronic pain medical treatment guidelines. These pain interventions and treatments not adapted directly from ODG but recommended by the DWC are labeled "[DWC]." If an ODG section was moved without changes by DWC to another topic heading, the ODG section was identified as "[ODG]" to avoid confusion.

Specific changes reflected in the DWC chronic pain medical treatment guidelines (DWC 2008) are as follows:

1. Deletion of an ODG individual treatment topic when the treatment is addressed in another ODG chapter which has not been adopted

The individual treatment topics of Adhesiolysis and Neuroreflexotherapy were omitted from the chronic pain medical treatment guidelines because the text under the topic heading referred to the ODG low back chapter for the evidence review which is not part of the MTUS. The reason for deleting this reference is that DWC has not adopted other ODG chapters. DWC cannot make references to documents which are not formally adopted by reference in the rulemaking or are not part of the documents relied upon and made available to the public during the formal rulemaking process.

2. Modification of ODG chapter on pain's individual treatment topic heading

The individual treatment topic heading for Capsaicin, topical (chili pepper/ cayenne pepper) was modified to better reflect the topic. The ODG guideline text discussed the pharmaceutical formulations of capsaicin. It did not include a discussion on chili pepper or cayenne pepper. The topic heading was changed to delete the references to chili pepper and cayenne pepper to better reflect the substance of the guideline text. However, the ODG individual treatment topic was not changed and an evidence-based review was not conducted.

3. Sections of the ODG chapter on pain either modified or omitted

a. ODG sections on diagnostic tests not included in the chronic pain medical treatment guidelines because they have broader uses beyond chronic pain medical treatment

The following individual treatment topics contained in ODG chapter on pain were omitted from the chronic pain medical treatment guidelines because they represent diagnostic tests that are not exclusive to the diagnosis of chronic pain. Because these tests have application beyond chronic pain diagnosis, they were omitted from the chronic pain medical treatment guidelines as inclusion would cause the chronic pain medical treatment guidelines to override the clinical topics guidelines. This in turn would limit the use of these tests which is not the intention of the chronic pain medical treatment guidelines. Omitting these diagnostic tests from the chronic pain medical treatment guidelines will

allow application of the clinical topics guidelines of the MTUS. Further, it is beyond the scope of the chronic pain medical treatment guidelines to detail how these tests are used. The following is a list of the omitted individual treatment topics: Autonomic test battery, Current perception threshold (CPT) testing, Electrodiagnostic testing (EMG/NCS), Evoked potential studies, Neurometer®, Quantitative sensory threshold (QST) testing, Sensory nerve conduction threshold (sNCT) device, Stress infrared telethermography, and Thermography (infrared stress thermography).

b. ODG individual treatment topics not included in the chronic pain medical treatment guidelines as they are informative and/or educational in nature

The ODG chapter on pain contains various individual treatment topics that are informative and/or educational in nature. Although informative, these concepts are not treatment topics and do not substantively add to the overall utility of the chronic pain medical treatment guidelines. Moreover, these concepts/definitions are either discussed in part in the introduction of the chronic pain medical treatment guidelines or were determined not to serve a purpose in the guidelines and the MTUS. Further, because the chronic pain medical treatment guidelines are primarily used to assist in the provision of medical treatment by offering an analytical framework for the evaluation and treatment of injured workers and to help understand what treatment has been proven effective, DWC determined that streamlined guidelines would better serve the public. Accordingly, the ODG chapter on pain individual treatment topics not included in the chronic pain medical treatment guidelines are as follows: Comorbid psychiatric disorders, CRPS (complex regional pain syndrome), CRPS, diagnostic criteria, Diabetic neuropathy, Diagnostic criteria for CRPS, Fibromyalgia syndrome (FMS), Myofascial pain, Number needed to treat (NNT), RSD (reflex sympathetic dystrophy), Substance abuse (tolerance, dependence, addiction), Sympathetically independent pain (SIP), and Sympathetically maintained pain (SMP).

c. Individual treatment topics which already existed in the MTUS and therefore were not adapted from the ODG chapter on pain

The ODG chapter on pain individual treatment topic on acupuncture was not adopted into the chronic pain medical treatment guidelines. The DWC previously adopted the acupuncture medical treatment guidelines now contained in proposed Section 9792.24.1 of the California Code of Regulations, Title 8, under the Special Topics section of the MTUS. This section addresses the use of acupuncture for chronic pain in the workers' compensation system in California.

(d) Omission of ODG chapter on pain's bibliography/references from main text

The ODG chapter on pain's bibliography/references was omitted from the main text to streamline the treatment guidelines as ODG chapter on pain is very extensive (over 700 pages). The bibliography/references, including DWC's own evidence tables, are being made available to the public as separate document as these were documents relied upon during the formal rulemaking period. The bibliography/references are contained in a separate document entitled Appendix D—Chronic Pain Medical Treatment Guidelines (DWC 2008)—Division of Workers' Compensation and Official Disability Guidelines' References. Appendix D will be made available to the public in the rulemaking file and on the internet at http://www.dwc.ca.gov as part of the chronic pain medical treatment guidelines.

4. Restructuring of ODG chapter on pain's individual treatment topics

(a) General restructuring of ODG guidelines as adapted

Individual treatment topics found in ODG's chapter on pain are laid out in a table format in two columns wherein topic heading is located in the left column and the text for the individual treatment topic is located in the right column. DWC's chronic pain medical treatment guidelines as adapted from ODG was organized by topic heading in alphabetical order, and placing the individual treatment topic immediately underneath the topic heading thus eliminating the two column format.

(b) Restructuring of physical medicine individual treatment topics

Upon review of the ODG chapter on pain it was determined that it is more appropriate to group the physical therapy and occupational therapy individual treatment topics under the topic heading "Physical Medicine." This was done for practical purposes as the Division of Workers' Compensation Official Medical Fee Schedule (8 CCC 9789.10 et al.) organizes these therapies under the umbrella title of physical medicine. Based on this determination, the following changes were made:

(1) The text setting forth the individual treatment topic immediately below the ODG topic title "Physical Therapy" was moved to the new topic title "Physical Medicine."

(2) Text was inserted under the ODG "Physical Therapy" topic title stating: "See Physical Medicine."

(3) The text in the ODG "Occupational Therapy" Guideline was changed from "See Physical Therapy" to "See Physical Medicine."

(c) Restructuring of transcutaneous electrotherapy individual treatment topics

The individual treatment topics related to electrotherapy listed in alphabetical order in the ODG chapter on pain are as follows: Electroceutical therapy (bioelectric nerve block), Galvanic stimulation, H-wave stimulation (devices), Interferential current stimulation (ICS), Microcurrent electrical stimulation (MENS devices), Neuromuscular electrical stimulation (NMES), Neuroreflexotherapy, Percutaneous electrical nerve stimulation (PENS), Percutaneous neuromodulation therapy (PNT), RS-4i sequential stimulator, Spinal cord stimulation, Sympathetic therapy, TENS, chronic pain (transcutaneous electrical nerve stimulation), and TENS, post operative pain (transcutaneous electrical nerve stimulation). All but three of these individual treatment topics involve the delivery of electricity across the skin (transcutaneous). The other individual treatment topics are for devices that deliver electrical stimulation from inside the body (percutaneous and spinal cord stimulation).

In adapting the ODG Chapter on Pain, DWC determined that individual treatment topics for all forms of transcutaneous electrical stimulation should be grouped under the heading "transcutaneous electrotherapy." The purpose of the grouping under one heading is to show similarities and differences between the available devices used in treating pain and to compare their benefits. The restructuring of transcutaneous electrotherapy individual treatment topics is intended to present these individual treatment topics in a more cohesive manner as opposed to each having its own alphabetical listing as found in ODG. Given the common use of these devices and the proliferation of different device types, the grouping facilitates the use of the chronic pain treatment guidelines.

The term topic heading "transcutaneous electrotherapy" was chosen to avoid conflict with existing terminology for these devices, such as transcutaneous electrical nerve stimulation (TENS). According the Merriam-Webster dictionary, electrotherapy represents the therapeutic use of electricity (http://www.merriam-webster.com/dictionary/electrotherapy). It is important to note that the heading was also selected to differentiate these individual treatment topics from electrodiagnosis. The term electrotherapy connotes the broadest concept of therapeutic applications of electricity. *Electrodiagnosis* is "the use of electrical devices in the diagnosis of pathologic conditions." (Dorland's Illustrated Medical Dictionary, 31st Edition, p. 607.) Electrodiagnosis includes nerve conduction studies, evoked potentials, and electromyography. Electrodiagnosis is not part of the chronic pain medical treatment guidelines. The individual treatments discussed in these guidelines represent instances of electrotherapy.

DWC identified ODG's individual treatment topics for Electroceutical therapy (bioelectric nerve block), Galvanic stimulation, H-wave stimulation (devices), Interferential current stimulation (ICS), Microcurrent electrical stimulation (MENS devices), RS-4i sequential stimulator, Sympathetic therapy, TENS, chronic pain (transcutaneous electrical nerve stimulation), and TENS, post operative pain

(transcutaneous electrical nerve stimulation), and placed them under the category heading "transcutaneous electrotherapy" for the reasons set forth above. DWC further wrote an introductory paragraph which informs the public that electrotherapy represents the therapeutic use of electricity. The introductory paragraph informs the public that there are many uses of electrotherapy in pain, the most common of which is transcutaneous electrical stimulation devices. The introductory paragraph further informs the public that the list provided are individual treatment topics for different commercially available types of transcutaneous electrotherapy devices used to treat pain.

In its chapter on pain, ODG included percutaneous electrical nerve stimulation (PENS), percutaneous neuromodulation therapy (PNT), and spinal cord stimulation in its individual treatment topics related to electrotherapy. These topics were left in alphabetical order in the chronic pain medical treatment guidelines, but were excluded from the category heading of transcutaneous electrotherapy as they are not transcutaneous treatments. Moreover, the individual treatment topic for Neuroreflexotherapy was omitted from the chronic pain medical treatment guidelines because the text under the topic heading referred to the ODG low back chapter which is not part of the MTUS. The reason for deleting this reference has been explained above.

The original ODG's individual treatment topics titles for Electroceutical therapy (bioelectric nerve block), Galvanic stimulation, H-wave stimulation (devices), Interferential current stimulation (ICS), Microcurrent electrical stimulation (MENS devices), Neuromuscular electrical stimulation (NMES), RS-4i sequential stimulator, Sympathetic therapy, TENS, chronic pain (transcutaneous electrical nerve stimulation), and TENS, post operative pain (transcutaneous electrical nerve stimulation), were left alphabetically in the chronic pain medical treatment guidelines. The text under those titles now refers the reader to the transcutaneous electrotherapy topic heading where the individual treatment topics are found.

ODG contained a topic heading entitled "electrical stimulators (E-stim)" which served as a navigational tool directing the reader to the relevant individual treatment topics as found in the ODG chapter on pain. This topic heading now serves as a navigational tool directing the reader to relevant individual treatment topics as found in DWC's chronic pain medical treatment guidelines, and for transcutaneous devices it further refer the reader to DWC's trancutaneous electrotherapy topic heading.

(d) Restructuring of complex regional pain syndrome individual treatment topics

The individual treatment topics related to complex regional pain syndrome listed in alphabetical order in the ODG chapter on pain are as follows: CRPS (complex regional pain syndrome); CRPS, diagnostic criteria; CRPS, medications; CRPS, prevention;

CRPS, spinal cord stimulators (SCS); CRPS, sympathectomy; CRPS, sympathetic and epidural blocks; and CRPS, treatment.

In adapting the ODG individual treatment topics related to these topics, DWC selected the topic CRPS (complex regional pain syndrome) but clarified the name of the topic to state: ***Complex Regional Pain Syndrome (CRPS)*** as it was believed that the full name of the syndrome represented the topic better. The ODG individual treatment topic "CRPS (complex regional pain syndrome)" was left in alphabetical order in the main guideline and identified as "[DWC]" and the text immediately below the topic was changed to a navigational tool stating "See Complex Regional Pain Syndrome (CRPS)." The remaining individual treatment topics related to these topics, except CRPS, diagnostic criteria, were grouped under the new topic title ***Complex Regional Pain Syndrome (CRPS)***, and are now listed alphabetically as follows: CRPS, medications; CRPS, prevention; CRPS, spinal chord stimulators (SCS); CRPS, sympathectomy; CRPS, sympathetic and epidural blocks; and CRPS, treatment.

The individual treatment topic for CRPS, diagnostic criteria was not adopted for the reasons set forth below. (See, Individual treatment topics determined by the ODG chapter on pain to be "under study.")

4. Evidence-based reviews (EBR) conducted

During the pre-rulemaking period, the Administrative Director through the Medical Director, MEEAC, and the public (public comments received during the DWC Forums postings) identified treatment topics which required further review. DWC performed an EBR whenever it revised or added a treatment section to the chronic pain medical treatment guidelines. The EBR process followed the following general format although customized to the specific topic: (1) Topic, (2) Date of review, (3) Treatment recommendation, (4) Reason for review, (5) Background research, (6) Search criteria/terms, (7) Findings, (8) Strength of evidence, (9) MEEAC recommendations, and (10) Evidence lists.

(a) Added individual treatment topics

Labor Code section 5307.27 requires the Administrative Director to adopt an MTUS that is "scientific and evidence-based, peer-reviewed, and nationally recognized." (See, also Lab. Code, § 4604.5(b).) The statute requires the MTUS address, at a minimum, the frequency, duration, intensity, and appropriateness of all treatment procedures and modalities commonly performed in workers' compensation cases. (Lab. Code, § 5307.27) Further, the MTUS is presumed to be correct on the issue of extent and scope of medical treatment (Lab. Code, § 4604.5(a)).

In order to meet the requirements of the statute, DWC added topics to the chronic pain medical treatment guidelines (DWC 2008) which were not addressed by the ODG chapter on pain. These individual treatment topics are Cytokine Testing [DWC] and Topical Analgesics – Compounded [DWC]. EBRs were conducted and recommendations were included in the medical treatment guidelines (DWC 2008). (See, Appendix B—Chronic Pain Medical Treatment Guidelines (DWC 2008) Evidence-Based Reviews, for basis of these individual treatment topics.) Further, with regard to the text immediately below the original ODG topic heading for Salicylate topicals, DWC added a reference to the ODG text stating "See also Topical Analgesics – Compounded [DWC]." This sentence serves as navigational tool to refer the reader to the new DWC section entitled: Topical Analgesics – Compounded [DWC] as this section provides useful information to the reader on this topic. The DWC conducted EBRs on these individual treatment topics and added these guidelines to the MTUS identifying them as "[DWC]." (See, Appendix B—Chronic Pain Medical Treatment Guidelines (DWC 2008) Evidence-Based Reviews, for basis of these individual treatment topics.)

5. Individual treatment topics determined by the ODG chapter on pain to be "under study."

(a) EBRs required

The ODG chapter on pain uses the term "under study" for some individual treatment topics." The term "under study" indicates that the evidence was reviewed but ODG was unable to make a recommendation either in support or against the treatment based on the insufficiency of the evidence. Because the MTUS is presumed to be correct on the issue of extent and scope of medical treatment (Lab. Code, § 4604.5(a)), and because of the lack of guidance in the ODG chapter on pain on these topics, it was necessary for the DWC to conduct EBRs on these individual treatment topics to determine whether or not the treatment should be recommended. Just because the evidence is not sufficient, this does not necessarily mean that the individual treatment topic should not have a recommendation.

The ODG chapter on pain individual treatment topics labeled "under study" in this area are as follows: Autonomic test battery; Clonidine, intrathecal; Functional imaging of brain responses to pain; Intravenous regional sympathetic blocks (for RSD, nerve blocks); Ketamine; Neuromuscular electrical stimulation (NMES devices); Percutaneous electrical nerve stimulation (PENS); and Testosterone replacement for hypogonadism (related to opioids). DWC has made determinations as to whether or not to recommend them in its chronic pain medical treatment guidelines based on the EBRs conducted. (See, Appendix B—Chronic Pain Medical Treatment Guidelines (DWC 2008) Evidence-Based Reviews, for basis of these individual treatment topics.) Moreover, the individual

treatment topic for Neuroreflexotherapy, which was labeled by ODG as "under study," was omitted from the chronic pain medical treatment guidelines because the text under the topic heading also referred to the ODG low back chapter which is not part of the MTUS. The reason for deleting this reference has been explained above.

(b) EBRs not required

Some individual pain treatment topics in the ODG chapter on pain also indicated the term "under study." However these individual pain treatment topics did not require EBRs for the following reasons.

(i) Injection with anaesthetics and/or steroids

The original text immediately below ODG's section regarding "Injection with anaesthetics and/or steroids" had a general statement that injections with anaesthetics and/or steroids were "under study." However, ODG goes on to refer the reader to specific sections pertaining to various injections for which EBRs were already completed. Because the EBRs were already completed in connection with the specific individual treatment topics referenced, it was unnecessary for DWC to conduct its own EBRs. For organizational purposes ODG's topic title *"Injection with anaesthetics and/or steroids"* was converted into a navigational tool referring the reader to the appropriate individual treatment topics so that when a reader is looking for injections they are redirected to the specific injection type. Thus, the topic title now reads: "Injection with anaesthetics and/or steroids" [DWC], and the text immediately below indicates, "[s]ee Epidural steroid injections (ESI's), Lumbar sympathetic block, Trigger point injections, Stellate ganglion block, and Prolotherapy."

(ii) Milnacipran (Ixel®)

ODG indicates that the individual treatment topic for Milnacipran (Ixel®) is "under study." ODG indicates that the drug is not FDA approved and not available in the U.S. Based on this information, DWC has determined that the drug is not recommended, and there is no need to conduct an EBR at this time. The title of the individual treatment topic is now reflected as "Milnacipran (Ixel®) [DWC]" and the text states as follows: "Not Recommended. It is not FDA approved and not available in the US."

(iii) Chronic pain programs, early intervention and chronic pain programs, intensity

With regard to "[c]hronic pain programs, early intervention" and "[c]hronic pain programs, intensity," these individual treatment topics were determined by ODG to be "under study." They were not included in the chronic pain medical treatment guidelines

and EBRs were not conducted because these topics overlap philosophical concepts of the MTUS. For example, in *Part 1* of the guidelines setting forth the introduction to the chronic pain medical treatment guidelines, early identification of chronic pain patients is identified as a very important step in dealing with chronic pain. The MTUS philosophy also recognizes that the different aspects or constraints in different cases determine the levels of resources (i.e., program intensity) necessary for proper pain management. Because research continues to be conducted to determine the optimal configuration and timing of pain programs, DWC decided that it is more appropriate at this time not to include these specific individuals treatment topics in the chronic pain medical treatment guidelines but to emphasize the introduction of the chronic pain medical treatment guidelines as a general philosophy of the MTUS that incorporates some of the concepts from these omitted ODG individual treatment topics.

(iv) Chronic pain programs, opioids

This individual treatment topic was determined to be "under study." ODG states that "[t]here remains a need to assess the effects of interdisciplinary pain program on patients who remain on opioids throughout treatment, and to determine whether opioid use should be a screening factor for admission to a program." In light of ODG's recommendation, DWC determined that this section was duplicative of many individual treatment topics contained in the chronic pain medical treatment guidelines concerning the use of opioids. Patients who frequently enter pain programs have medication management problems and chemical dependency which at times is unrelated to opioids. Thus, to have a specific guideline for "chronic pain programs, opioids," when the area is still under study and the difficulty to manage opioids is addressed in other individual treatment topics, is not appropriate at this time.

(v) Facet blocks

This individual treatment topic was determined by ODG to be "under study." Facet blocks are an injection therapy for back pain when facet joint pain is suspected. Because DWC will soon begin the process of evaluating low back guidelines, it was determined that it is more appropriate to address this treatment topic when the low back guideline is addressed. Accordingly, the individual treatment topic for facet blocks is not included in the chronic pain medical treatment guidelines, and is deferred pending formal rulemaking for adoption of low back guidelines which will commence in the near future.

(vi) Massage therapy

This individual treatment topic was determined by ODG to be "under study." Upon review of this individual treatment topic, it was determined that massage therapy relates more to physical medicine as it is one of the modalities used in the course of physical

rehabilitation. For this reason, it was determined that it was not necessary to conduct an EBR. Accordingly, the individual treatment topic for massage therapy is not included in the chronic pain medical treatment guidelines.

(vii) CRPS, Diagnostic Criteria

This individual treatment topic was determined by ODG to be "under study." Furthermore, this guideline is informative and/or educational in nature. Although informative, the concepts contained in this guideline are not treatment topics, and do not substantively add to the overall utility of the chronic pain medical treatment guidelines. For further information see topic heading "ODG individual treatment topics not included in the chronic pain medical treatment guidelines as they are informative and/or educational in nature," above.

(6) California specific topic related to reduction of pharmaceutical drug diversion not included in the ODG chapter on pain added to the chronic pain medical treatment guidelines (DWC 2008)

The ODG chapter on pain contains a comprehensive section on the use of opioids. However, to adapt the ODG chapter on pain for use in California, it is important to reference California's *Controlled Substance Utilization Review and Evaluation System* (CURES). This program is run by the Bureau of Narcotic Enforcement and is intended to assist in the reduction of pharmaceutical drug diversion without affecting legitimate medical practice and patient care. (Office of the Attorney General, Bureau of Narcotic Enforcement, *Cures Program*,http://ag.ca.gov/bne/trips.htm). Accordingly, a California specific individual medical treatment topic was added into the Opioids category of chronic pain medical treatment guidelines to reflect this program. A hardcopy of the CURES program website address and description of the program is included in the rulemaking file as a document relied upon and in support of this individual treatment topic. Because this guideline is based on the CURES program there is no need to conduct an EBR. (See topic heading in the chronic pain medical treatment guidelines entitled: "Opioid/California Controlled Substance Utilization Review and Evaluation System (CURES) [DWC]" for further information.

(7) Replaced ODG individual treatment topic recommendations (listed alphabetically)

DWC replaced the recommendations for the following ODG individual treatment topics: Boswellia Serrata Resin (Frankincense), Cod liver oil, Curcumin (turmeric), Glucosamine (and Chondroitin Sulfate), Green tea, Herbal medicines (note this individual treatment has been converted into a navigational tool), Pycnogenol (maritime pine bark), Uncaria Tomentosa (Cat's Claw), and White willow bark. Herbal therapies

and nutritional supplements and are not considered drugs by the FDA, rather they are considered foods or dietary supplements.

Labor Code section 5307.27 requires the Administrative Director to adopt an MTUS that incorporates evidence-based, peer-reviewed, nationally recognized standards of care, and that addresses the frequency, duration, intensity, and appropriateness of all treatment procedures and modalities commonly performed in workers' compensation cases. The Federal Drugs Administration (FDA) does not regulate the manufacturing of foods or dietary supplements listed above:

> Currently, there are no FDA regulations that are specific to dietary supplements that establish a minimum standard of practice for manufacturing dietary supplements. However, [the] FDA intends to issue regulations on good manufacturing practices that will focus on practices that ensure the identity, purity, quality, strength and composition of dietary supplements. At present, the manufacturer is responsible for establishing its own manufacturing practice guidelines to ensure that the dietary supplements it produces are safe and contain the ingredients listed on the label. (See, U.S. Food and Drug Administration, Center for Food Safety and Applied Nutrition, January 3, 2001, Overview of Dietary Supplements. http://vm.cfsan.fda.gov/~dms/ds-oview.html.)

Thus, recommending these individual treatment topics would not conform to the requirements of the Labor Code section 5207.27 requiring that the MTUS address the "intensity" of treatment. The MTUS will be revised when the FDA issue regulations on good manufacturing practices that will focus on practices that ensure the identity, purity, quality, strength and composition of dietary supplements.

(8) Non-substantive changes

(a) In certain circumstances, headings were added and/or modified to serve as navigational tools (links) or index entries which refer to other related sections.

(b) Links to applicable regulations (e.g., Medical Board of California or MTUS) were added.

(c) References found in other treatment sections in the ODG chapter on pain which referred back to the sections deleted or modified treatment by the DWC (e.g., dead links) were removed.